

Applicant: Michael R. Rosen et al.
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at
multiple electrode pairs for contacting an epicardial surface of heart and for delivering periodic pacemaker signals to the epicardial surface through said electrode pairs, to alter the effective refractory period in the heart, wherein the electrode pairs are arranged in two columns with one electrode in each pair in one column, and the other electrode in each pair in the other column.

60. A device for treating a heart to induce ion channel remodeling comprising a substrate having linked multiple electrode pairs for contacting an epicardial surface of heart and for delivering periodic pacemaker signals to the epicardial surface through said electrode pairs, to induce ion channel remodeling in the heart, wherein the electrode pairs are arranged in two columns with one electrode in each pair in one column, and the other electrode in each pair in the other column.

In the Abstract:

Please replace the Abstract with the replacement Abstract attached as Exhibit B.

REMARKS

Reconsideration and allowance in view of the amendments made and comments which follow are respectfully requested.

Claims 1-57 were pending. Claims 5, 9, 12, 20, 24, 28, 31, 43, 47 and 50 are being amended, and claims 58-60 are being added. Claims 1-60 are now pending.

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In the Office Action dated March 13, 2001, the Examiner objected to the Abstract of the disclosure because of the language "said". The Abstract is being amended in lines 7 and 8 to change "said" to "the".

The Examiner rejected Claims 5, 9, 24, 28, 43, and 47 under 35 U.S.C. §112 because of the following:

In claim 5, it is unclear if "a heart" is the same "a heart" of claim 1,

In claims 5 and 9, it is unclear if "an epicardial surface" is the same "an epicardial surface" of claim 1,

In claim 24, it is unclear if "a heart" is the same "a heart" of claim 20,

In claims 24 and 28, it is unclear if "an epicardial surface" is the same "an epicardial surface" of claim 20,

In claim 43, it is unclear if "a heart" is the same "a heart" of claim 39, and

In claims 43 and 47, it is unclear if "an epicardial surface" is the same "an epicardial surface" of claim 39.

In response, claims 5, 9, 24, 28, 43 and 47 have been amended to change "an" and "a" to "the" in the passages objected to.

The Examiner rejected claims 1, 2, 9-13, 20-21, 28-32, 39-40, and 47-51 under 35 U.S.C. 102(b) as being allegedly anticipated by Knisley (U.S. Patent No. 5,824,028). The Examiner stated that

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Knisley discloses a method and device with electrode(s) oriented relative to cardiac fiber direction whereby the stimulation pulse reduces the non-uniformity of the transmembrane voltage change associated with arrhythmic conditions.

The Examiner stated that Knisley includes an electrical pulse generator (26), a lead assembly (25), and a plurality of linear electrodes (12), focuses on the transmembrane potential and ion channels (column 1, lines 11-54) and recognizes the impact of treatment on the refractory period (column 3, lines 43-49). The Examiner stated that the electrode can be inserted in the myocardium, positioned to contract the epicardium or endocardium, or be a flat ribbon (column 2, lines 31-46), and that sutures (column 2, line 66 - column 3, line 2) can attach the electrode. The Examiner stated that Knisley discusses alternate leads and electrode combinations to optimize polarity, timing and waveform shape (column 3, 23-34).

The Examiner also rejected claims 1, 10-12, 20, 29-31, 39, and 47-50 under 35 U.S.C. 102(b) as being allegedly anticipated by Kroll et. al. (U.S. Patent No. 5,366,485). The Examiner stated that Kroll et. al. disclose a defibrillation pretreatment of a heart, where a train of pulses are applied a fibrillating heart to organize the action of the chaotically contracting myocardial cells. The Examiner stated that the pretreatment system includes a power unit (12), conductors (14), and epicardial patches (16 and 18). The Examiner stated that the goal of the pretreatment is to increase the spatial organization of cells in the cardiac muscle (column 6, lines 34-53). The Examiner stated that the pretreatment pulses address the heart-cell functions including the ion-pump mechanism, the voltage of the body fluid around the cells, the myocardial cell membrane and the refractory period (column 4, lines

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46 - column 5, line 45). The Examiner stated that the pretreatment pulse can be varied relative to timing, length, height, polarity, pacing, and waveform (column 12, lines 10-25). The Examiner stated that the use of patch, subcutaneous or endocardial electrodes with the pretreatment system is disclosed (column 7, lines 43-47), and that the use of multiple electrode pairs is disclosed (column 2, lines 19-22).

The Examiner rejected claims 3, 7-8, 14, 17-19, 22, 26-27, 33, 36-38, 41, 45-46 and 52, 55-57 under 35 U.S.C. 103(a) as being allegedly unpatentable over Knisley in view of Dahl et. al. (U.S. Patent No. 5,203,348). The Examiner stated that Knisley discloses the claimed invention except for:

- the electrode strip of polyurethane (claims 3, 14, 22, 33, 41 and 52),
- the electrode comprised of platinum or consisting essentially of unalloyed platinum (claims 7-8, 17-18, 26-27, 36-37, 45-46, 55-56), and
- the electrode connected to an insulated stainless steel wire (claims 19, 38, and 57).

The Examiner stated that Dahl et. al. disclose an electrode and teaches that it is known to fabricate an electrode with a platinum or platinum alloy conductor or conductor with a stainless steel core (column 20-36), and a lead with a medical grade polyurethane sheath and a stainless steel coated conductor (column 5, lines 23-38). The Examiner stated it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the electrode and lead as taught by Knisley, with the

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materials of construction as taught by Dahl et. al., and that one having ordinary skill in the art would have been motivated to make such a modification in electrode and lead to gain improved electrical properties.

The Examiner rejected claims 4-6, 15-16, 23-25, 34-35, 42-44, and 53-54 under 35 U.S.C. 103(a) as being allegedly unpatentable over Knisley and Dahl et. al. in view of Ideker (U.S. Patent No. 5,873,893). The Examiner stated that modified Knisley discloses the claimed invention except for:

- electrode strip dimensions being about 7 cm x 1 cm, (claims 4, 23, and 42),

- the electrode pairs arranged in two columns (claims 5, 15, 24, 34, 43, and 53), and

- the electrode pair being about 2 mm apart and the electrode pairs being about 5 mm apart (claims 6, 16, 25, 35, 44, and 54).

The Examiner stated that Ideker discloses a cardiac device for reducing arrhythmia and teaches that it is known to use an electrode configuration of an elongated primary strip having a plurality of electrodes positioned at spaced intervals, e.g. 1-4 millimeters (column 3, lines 2-4), along its length. The Examiner stated, while this reference shows the electrode pairs oriented parallel to the longer axis of the strip, it would be an obvious design choice to orient the electrode pairs perpendicular to the longer axis of the strip. The Examiner stated that length of the electrode strip and specific electrode spacing is also seen as an obvious design choice based on the specific situation and treatment plan. The Examiner stated that it would have been obvious to one having ordinary skill in the art at the time the invention was made

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to modify the electrode as taught by the modified Knisley device, with the elongated primary strip as taught by Ideker, and that one having ordinary skill in the art would have been motivated to make such a modification in electrode to gain a more focused area for electrical stimulation.

In response to the Office Action, without conceding the correctness of the Examiner's position, but solely to advance prosecution, independent apparatus claims 12, 31 and 50 are being amended to more positively recite a pacemaker. Method claim 20 is being amended to recite that the electrical signals applied are periodic. The other amendments being made to the claims address the §112 rejections.

U.S. Patent No. 5,824,028 to Knisley relates to a device for delivering an electrical stimulation pulse to a heart, allegedly for cardiac pacing, defibrillation and the termination of tachycardia. The stimulation pulse is provided by an electrical pulse generator. This reference fails to teach or suggest that the electrical signals can be in the form of periodic electrical signals from a pacemaker, or that gap junctions will be remodeled. Accordingly, applicants believe that method claim 1 is patentable over Knisley.

Applicants also believe that independent method claims 20 and 39 are patentable over Knisley, because Knisley does not teach or suggest using periodic electrical signals from a pacemaker, or that the effective refractory period will be altered, or that an ion channel will be remodeled. Knisley at most suggests the use of an electrical pulse, but an electrical pulse is not a periodic pacemaker signal.

Applicants believe that independent apparatus claims 12, 31 and 50

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are patentable over Knisley because Knisley does not teach, suggest or render obvious a pacemaker for delivery periodic pacemaker signals to the epicardial surface through electrode pairs. Knisley at most suggests the use of an electrical pulse, but an electrical pulse is not a periodic pacemaker signal.

U.S. Patent No. 5,366,485 to Kroll relates to a defibrillator, and more particularly to an improved defibrillator wherein a number of pretreatment pulses are applied before a final monophasic defibrillation pulse. All of the pulses are applied through the same pair of electrodes (See column 11, lines 56-58; See also column 4, lines 8-9).

No where does Kroll discuss or even mention or suggest remodeling gap junctions. Moreover, Kroll expressly teaches away from using multiple electrode pairs. Accordingly, applicants believe that claims 1 and 12, directed to a method and apparatus, respectively, for remodeling gap junctions and using linked multiple electrode pairs, are patentable over this reference.

Applicants further believe that claims 20 and 31, directed to a method and apparatus, respectively, for altering the effective refractory period of a heart, is patentable over Kroll because Kroll does not teach or suggest, and actually teaches away from, using linked multiple electrode pairs, and does not teach or suggest altering the effective refractory period of a heart.

Applicants also believe that claims 39 and 50, directed to a method and apparatus, respectively, for inducing ion channel remodeling, is patentable over the Kroll reference because Kroll does not teach or suggest, and actually teaches away from, using linked multiple electrode pairs, and does not teach or suggest inducing ion channel remodeling of a heart.

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In view of the foregoing, applicants believe that all of the independent method and apparatus claims are patentable over Knisley and Kroll. For at least the same reasons, the dependent claims should be patentable as well.

Applicant have added claims 58, 59 and 60. Claim 58 is original claim 15 rewritten in independent form. Claim 59 is original claim 34 rewritten in independent form. Claim 60 is original claim 53 rewritten in independent form.

Original claims 15, 34 and 53 were rejected as allegedly obvious on the combination of Knisley, Dahl et. al., and Ideker.

Applicants believe that one skilled in the art would not be motivated to combine Knisley, Dahl et. al. and Ideker because Knisley is for the purpose of cardiac pacing, defibrillation and termination of tachycardia, whereas Dahl et. al. is only for the purpose of defibrillation and Ideker is for the purpose of reducing arrhythmias. Further, each electrode configuration of these references is different for its stated purpose. The Knisley electrode arrangement is only two large electrodes placed on the heart, and receive only a pulse, the Dahl et. al. electrode arrangement includes a variety including linear, are placed under the skin and not on the heart, are large and receives defibrillation pulses, and the Ideker electrode arrangement appears to be a linear array and delivers a trapezoidal pulse. While Ideker Figure 5 appears to show a plurality of strips, including a main strip and secondary strips, the secondary strips receive less current than the main strip, and thus by definition cannot be linked to the main strip.

In contrast, the presently claimed invention of claims 58, 59 and 60 comprises linked multiple electrode pairs in columns, to receive

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periodic pacemaker signals to obtain gap junctional remodeling, alteration of the effective refractory period or to induce ion channel remodeling, respectively, none of which is taught or rendered obvious by the combination proposed by the Examiner.


If a telephone interview would be of assistance in advancing prosecution of the subject application, the undersigned attorney invites the Examiner to telephone him at the telephone number provided below.

No fees, other than the fees for additional claims, are believed to be due in connection with the filing of this communication. If any other fee is due, or if the amounts submitted are insufficient, please charge deposit account number 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:
Assistant Commissioner for Patents,
Washington, D.C. 20231.

 6-13-01
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Mark Up Copy of Claims Showing Amendments Made:

5 5. (Amended) The method according to claim 1, wherein the step of
contacting comprises contacting linked multiple electrode pairs to
the epicardial surface of the heart, wherein the linked multiple
electrode pairs are arranged in two columns with one electrode in
each pair in one column, and the other electrode in each pair in
10 the other column.

9. (Amended) The method according to claim 1, wherein the step of
contacting comprises sewing a substrate strip containing linked
multiple electrode pairs to the epicardial surface of the heart.

15 12. (Amended) A device for treating a heart to obtain gap
junctional remodeling, comprising a substrate having linked
multiple electrode pairs for contacting an epicardial surface of a
heart and a pacemaker for delivering periodic pacemaker electrical
20 signals to the epicardial surface through said electrode pairs, to
remodel gap junctions in the heart.

20. (Amended) A method of treating a heart to alter the effective
refractory period, comprising contacting linked multiple electrode
25 pairs to an epicardial surface of a heart, and connecting the

electrode pairs to a pacemaker to apply periodic electrical signals to the epicardial surface, said signals being applied for a sufficient time and having characteristics sufficient to alter the effective refractory period of the heart.

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24. (Amended) The method according to claim 20, wherein the step of contacting comprises contacting linked multiple electrode pairs to the epicardial surface of the heart, wherein the linked multiple electrode pairs are arranged in two columns with one electrode in each pair in one column, and the other electrode in each pair in the other column.

28. (Amended) The method according to claim 20, wherein the step of contacting comprises sewing a substrate strip containing linked multiple electrode pairs to the epicardial surface of the heart.

31. (Amended) A device for treating a heart to alter the effective refractory period, comprising a substrate having linked multiple electrode pairs for contacting an epicardial surface of a heart and a pacemaker for delivering periodic pacemaker electrical signals to the epicardial surface through said electrode pairs, to alter the effective refractory period in the heart.

43. (Amended) The method according to claim 39, wherein the step of contacting comprises contacting linked multiple electrode pairs

to the epicardial surface of the heart, wherein the linked multiple electrode pairs are arranged in two columns with one electrode in each pair in one column, and the other electrode in each pair in the other column.

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47. (Amended) The method according to claim 39, wherein the step of contacting comprises sewing a substrate strip containing linked multiple electrode pairs to the epicardial surface of the heart.

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50. (Amended) A device for treating a heart to induce ion channel remodeling, comprising a substrate having linked multiple electrode pairs for contacting an epicardial surface of a heart and a pacemaker for delivering periodic pacemaker electrical signals to the epicardial surface through said electrode pairs, to induce ion

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channel remodeling in the heart.